

### REMARKS/ARGUMENTS

1. Claims 9-12 and 35-58 are pending and stand rejected under 35 U.S.C. 112 as being indefinite and as failing to comply with the enablement requirement and under 35 U.S.C. 103(a) as being unpatentable over Budowsky.
2. Applicants acknowledge with appreciation the courtesy of a telephonic interview on November 30, 2006 between Examiner David Sorkin, Supervisory Patent Examiner Wanda Walker, and Applicants' Attorney Jeffrey Klayman to discuss the Office action of October 17, 2006 and particularly the rejections under 35 U.S.C. 112. Based on the discussions with Mr. Sorkin and Ms. Walker, it is the understanding of Applicants' Attorney that there are essentially two main "112" issues, as follows:
  - a. According to its preamble, claim 1 is directed to a method of combining a first substance with a second substance. Because the last claim element makes the mixing of a first solution with the second substance to effectively combine the first and second substances conditional (i.e., "only if" mixing can be completed), however, there are situations in which implementation of the process will not result in combining the first and second substances as called out in the preamble. Thus, claim 1 is essentially a process control method rather than a method of combining substances.
  - b. The claims refer to a "predetermined useful lifetime" of a first solution. The Examiners have rejected this element, and particularly the word "useful," as being indefinite and non-enabled because the application does not describe

criteria for defining the usefulness of the first solution or how to predetermine the "useful" lifetime and only provides trademarks rather than a specific description of a particular compound. Applicants' Attorney explained that "predetermined" essentially means "determined in advance" and explained that the method does not require actually determining the useful lifetime but instead requires determining whether mixing of the first solution with the second substance can be completed within some predetermined useful lifetime of the first solution, e.g., based on the amount of time that has elapsed since the first solution was produced. The Examiners still felt that, in order to practice the claimed method, a person would need to be able to determine a useful lifetime for the first solution and would therefore need to understand the compound and the criteria for determining usefulness of the solution. It was suggested that the "112" rejections might be overcome by removing "predetermined useful lifetime" and instead focusing on the temporal aspects of the method.

3. Based on the discussions with the Examiners summarized above, Applicants have amended the claims as follows.

First, amended claim 9 is no longer directed to a method for combining a first substance with a second substance, but instead is directed to a method for use in a system for combining a first substance with a second substance.

Second, claim 9 no longer requires determining whether mixing of the first solution with the second substance can be completed within a predetermined useful lifetime of the first solution, but instead requires maintaining a timer to monitor the age of the first solution, determining whether mixing of the first solution with the second substance can be completed prior to an expiration time for the first solution based on the timer, and mixing the first

solution with the second substance only if it is determined that such mixing can be completed prior to the expiration time. These amendments are supported in the application, for example, at page 18 lines 3-11 (The process controller 120 maintains various timers, including a system time and date, a running timer for the process controller, and various process timers associated with the pumps ... The process controller 120 keeps track of the age of working solution, and prevents blood processing operations if the working solution becomes too old) and at page 40 in table 1 (if anomaly is that the working solution timer is about to expire, then the working solution is too old).

Claims 35-39, 43-45, 49-53, 57, and 58 have been amended to comport with amended claim 9.

Applicants respectfully submit that the rejections under 35 U.S.C. 112 have been traversed.


4. With regard to the rejection under 35 U.S.C. 103(a), Applicants respectfully submit that Budowsky does not maintain a timer to monitor the age of working solution, determine whether mixing of the solutions can be completed prior to an expiration time for the first solution based on the timer, and mixing the solutions only if it is determined that such mixing can be completed prior to the expiration time, as in amended claim 9. Thus, Applicants respectfully submit that the claims are allowable over Budowsky.

5. All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicant respectfully requests early allowance of the application. The Applicant requests that the Examiner contact the undersigned, Jeffrey T. Klayman, if it will assist further examination of this application.

6. Applicants petition for a three month extension of time. In the event that a further extension is needed, this conditional petition of extension is hereby submitted, and Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

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Respectfully submitted,



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